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PATENT COOPERATION TREATY

REC'D 15 MAY 2001
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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

11

Applicant's or agent's file reference 3875-4000PC1	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/19902	International filing date *(day/month/year)* 31 AUGUST 1999	Priority date *(day/month/year)* 31 AUGUST 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant THE RESEARCH FOUNDATION OF THE STATE UNIVERSITY OF NEW YORK		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☒ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 MARCH 2000	01 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL PAK Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/19902

I. Basis f the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-60, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the claims:
pages 61-68, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the drawings:
pages 1-9, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:
pages 1-20, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/19902

III. Non-establishment of opinion with regard t novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 23-31, 39, 47-52, and 54-68

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. (See Attached) .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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IV. Lack of unity f inventi n

1. In response to the invitation to restrict or pay additional fees the applicant has:

   [X] restricted the claims.

   [ ] paid additional fees.

   [ ] paid additional fees under protest.

   [ ] neither restricted nor paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   [ ] complied with.

   [X] not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   [ ] all parts.

   [X] the parts relating to claims Nos. 1-21, 32-38, and 40-45 .

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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V. Reasoned statement under Article 35(2) with r gard to novelty, inventive step or industrial applicability; citati ns and explanati ns supporting such statement

1. statement

Novelty (N)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Inventive Step (IS)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Industrial Applicability (IA)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO

2. citations and explanations (Rule 70.7)

Claims 1-10, 12-15, 17-22, 32-36, 38, and 40-44 lack novelty under PCT Article 33(2) as being anticipated by SHI et al.

SHI et al. disclose nucleic acid molecule encoding ERG1, ERG2, and ERG3(figures 1-3 and Table 1). SHI et al. disclose the vector comprising the above nucleic acid molecule and host cells comprising the vectors (pages 9423-9425; figures 1-8).

Claims 11, 16, 37, and 45 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest hte claimed products.

Claims 1-21, 32-38, and 40-45 meet the criteria set out in PCT Article 33(4), because the products can be used for diagnostics.

---------- NEW CITATIONS ----------

NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:
The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): C07K 14/00, 14/435; C12N 5/16, 15/12, 15/63, G01N 33/53, 33/566 and US Cl.: 435/6, 7.2, 320.1, 325; 530/350; 536/23.5

III. NON-ESTABLISHMENT OF REPORT:

No international search report has been established for claim numbers 23-31, 39, 47-52, and 54-68 .

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:
This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-21, 32-38, and 40-45, drawn to an isolated nucleic acid.
Group II, claim(s) 22, drawn to an isolated polypeptide.
Group III, claim(s) 46, drawn to a method for identifying a compound.
Group IV, claim(s) 53, drawn to a method of detecting the prsence of elk1.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because the product of claim 1 is anticipated by SHI et al. (J. Neuroscience. 15 December 1997. Vol. 17, No. 24, pp. 9423-9426) and thus, does not share a special technical feature with any other group.

The special technical feature of Group I is a nucleic acid, vector and host cell. Pursuant to 37 CFR 1.475(d), these claims are considered by the ISA/US to constitute the main invention, and none of the related groups II-XII correspond to the main invention.

The product of Group II does not share the same or corresponding special technical feature with Group I, because they are drawn to products having materially different structures and functions, and each defines a separate invention over the art.

The methods of Groups III-IV, do not share the same or corresponding special technical feature with each other, because the methods have materially different process steps and are practiced for materially different purposes, and each defines a separate invention over the art.

Since Groups I-IV do not share a special technical feature, unity of invention is lacking.

V. 1. REASONED STATEMENTS:
The report as to Novelty was positive (YES) with respect to claims 11, 16, 37, and 45.
The report as to Novelty was negative (NO) with respect to claims 1-10, 12-15, 17-21, 32-36, 38, 40-44 .
The report as to Inventive Step was positive (YES) with respect to claims 11, 16, 37, and 45 .
The report as to Inventive Step was negative (NO) with respect to claims 1-10, 12-15, 17-21, 32-36, 38, 40-44.
The report as to Industrial Applicability was positive (YES) with respect to claims 1-21, 32-38, 40-45 .
The report as to Industrial Applicability was negative (NO) with respect to claims NONE .